UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA, *et al.*,
ex rel. JOSEPH PIACENTILE and
KEVIN B. KILCOYNE,

Plaintiffs,

No. 04-CV-3983 (SJ)(RML)

v.

MEMORANDUM AND ORDER

AMGEN, INC.; US ONCOLOGY, INC.; AMERISOURCE BERGEN CORPORATION; AMERISOURCE BERGEN SPECIALTY GROUP; INTERNATIONAL PHYSICIANS NETWORK and INTERNATIONAL ONCOLOGY NETWORK,

Defendants.
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A P P E A R A N C E S:

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JOHNSON, Senior District Judge:

Relators Joseph Piacentile and Kevin B. Kilcoyne bring this *qui tam* action on behalf of the United States, the District of Columbia and 21 states, alleging, *inter alia*, that Kilcoyne's former employer, Amgen, Inc. ("Amgen"), and U.S.

Oncology, Inc. ("U.S. Oncology" or "Defendant") violated, and conspired to violate, the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. (the "FCA") and similar state statutes. U.S. Oncology now moves to dismiss the action against it, principally alleging that Relators' Third Amended Complaint (the "TAC") fails to allege the particularized facts necessary to state a claim under the FCA or analogous state statutes. For the reasons set forth below, that motion is granted and this action is dismissed without prejudice to filing a Fourth Amended Complaint within thirty (30) days of the date of this Memorandum and Order.

BACKGROUND

Except as otherwise stated, the following facts are drawn from the TAC and are assumed to be true for purposes of this motion. Amgen is a pharmaceutical company which manufactures and markets various prescription drugs, including Aranesp, Neulasta and Neupogen (collectively, the "Drugs") (25).[1] Aranesp is Amgen's brand name for darbopotein alfa, a protein that stimulates the production of red blood cells (60). The U.S. Food and Drug Administration (the "FDA") has approved Aranesp for the treatment of anemia associated with chronic renal failure and anemia in patients with non-myeloid malignancies (*i.e.*, cancers not involving or affecting the bone marrow) where the anemia is due to the effect of concomitantly administered chemotherapy (60). Aranesp competes with epotein alfa—another protein which has been approved by the FDA for the treatment of

[1] Numbers in parentheses denote paragraphs in the TAC.

nearly identical indications (61). Although Amgen itself developed epotein alfa, it sold the rights to market it to Ortho Biotech Products, Inc., which markets it under the trade name Procrit (61).

Neupogen and Neulasta are both granulocyte colony-stimulating factors (G-CSFs), which stimulate the production of white blood cells (62-63). Both drugs have been approved by the FDA to treat oncology patients who are receiving myelosuppressive anti-cancer drugs (*i.e.*, drugs that suppress the bone marrow's production of red blood cells or platelets) to fight non-myeloid malignancies (62-63). By stimulating the production of white blood cells, Neupogen and Neulasta reduce the incidence of infection in these patients (62-63).

One of the principal purchasers of the Drugs is the federal government, which reimburses physicians and other providers for administering them to patients who receive benefits under Medicare, Medicaid, or other federal programs (25). In order for their drugs to be eligible for Medicaid reimbursement, drug manufacturers must provide "best price" information to the federal Centers for Medicare and Medicaid Services ("CMS"), a division of the U.S. Department of Health and Human Services ("HHS") that administers Medicare and Medicaid (28, 55). The Medicaid Rebate Statute ("MRS"), 42 U.S.C. § 1396r-8, defines "best price" as including "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under [the MRS])" (57) (quoting 42 U.S.C.A. § 1396r-8(c)(1)(C)(ii)). The CMS uses this "best price"

information to calculate rebates payable by the drug manufacturers to the Medicaid program. (55).

Similarly, the drug manufacturers must provide Average Manufacturers Price information to CMS (56). "Off-invoice discounts" are not reflected in the sales data reported to Medicaid and Medicare (83). Unless the customer reports these off-invoice discounts, "the prices reported to the Government that form the basis of the customer's reimbursement under Medicaid and Medicare are falsely inflated" (83).

Amgen's Illegal or Unlawful Practices

The TAC alleges that Amgen has engaged in at least four illegal or unlawful practices in order to promote the sale of the Drugs and to gain market share in its competition with Procrit. First, Amgen routinely offered price discounts and paid "kickbacks" to physicians in order to induce them to prescribe the Drugs (87). The kickbacks take several forms, including "cash payments, so-called research grants, free services, free equipment and other inducements" (88). According to the TAC, these discounts and kickbacks violate the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, which prohibits, *inter alia*, the payment or receipt of any remuneration (including any kickback, bribe, or rebate) in return for the purchase of any good for which payment may be made in whole or in part under a Federal health care program (37). The TAC acknowledges that the AKS "contains statutory exceptions and regulatory 'safe harbors' excluding certain types of

conduct from liability," but specifically alleges that none of these apply "to Defendants' conduct in this matter" (40).

Second, Amgen illegally "marketed the spread" between the discounted price that it charged its customers for Aranesp and the amount of reimbursement paid to those customers by the Government for administering the drug. Amgen created this "spread" by structuring its contracts to provide its customers with "off-invoice discounts, volume discounts and rebates based on the customer's market share of Aranesp," which were not reported to the Government and, accordingly, not included in the reimbursement calculations (5, 64). Amgen then supplied its sales representatives with "cost calculators" and "rebate estimators," and directed them to market the "savings" that a customer could earn by increasing purchases of Aranesp (66). Sales representatives were specifically instructed to compare the spread earned on Aranesp to the spread earned on purchases of Procrit, in an effort to persuade health care providers to prescribe Aranesp instead of its competitor (76).

Amgen also competed with Procrit through a third unlawful technique: tying price concessions for purchases of G-CSFs to purchases of Aranesp. For example, Amgen's Enhanced Momentum II contract provided customers with "progressively increasing 'off-invoice discounts' on Neupogen and Neulasta based on the customer's purchases of Aranesp" (83). Similarly, under the Total Oncology Partner Program, "quarterly increases in a customer's combined

purchases of all Amgen products earns the customer rebates on Neulasta and Neupogen purchases" (85). The TAC alleges that these tying and bundling arrangements violated the AKS and HHS regulations prohibiting the practice of "reducing the price of one good in connection with the purchases of a different good," as well as "best price regulations" (82, 86).

Fourth, Amgen "actively engaged in a clandestine off-label marketing scheme for … Aranesp and Neulasta" (107). According to the TAC, Amgen encouraged its sales representatives to market the drugs for uses not specifically approved by the FDA, including some uses for which Procrit alone has been FDA-approved (108-113, 123). In addition, Amgen retained Health Dimensions, Inc., to recruit and pay influential physicians to lecture other healthcare providers on prescribing Aranesp and Neulasta for off-label indications, and paid for the hotel rooms, flights and meals of providers attending these lectures (115-21) Because this off-label marketing scheme, if known to the FDA, would result in administrative action that would halt Government reimbursement for Aranesp and Neulasta, Amgen concealed the scheme (125-28).

This Action

In September 2004, Relator Joseph Piacentile commenced this *qui tam* action on behalf of the United States and against Amgen and U.S. Oncology, Inc.—one of Amgen's major customers—alleging that these defendants violated four provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*. Although

Piacentile, who describes himself as "a licensed, non-practicing physician engaged in the healthcare industry" (20), has never been employed by Amgen or U.S. Oncology, he claims to have conducted an "extensive internal investigation" in which he personally "secured admissions from top marketing executives" at Amgen and U.S. Oncology relating to the wrongdoing alleged in the complaint (21). He also alleges that he is unaware of any "public disclosure" relating to the false claims at issue and that he is, in any event, an "original source" of the information alleged in the pleading (24).

In April 2007, Piacentile filed an Amended Complaint, again naming only Amgen and U.S. Oncology as defendants. The Amended Complaint added Kevin B. Kilcoyne as a relator. Unlike Piacentile, Kilcoyne is a former employee of Amgen, which employed him as a Professional Sales Representative from September 1990 to May 2005 (22).

In June 2009, Relators filed a Second Amended Complaint, which added four new defendants: Amerisource Bergen Corporation ("ABC"), Amerisource Bergen Specialty Group ("ABSG"), International Physicians Network ("IPN") and International Oncology Network ("ION"). These four defendants (collectively, the "ABC Defendants") are related. ABSG—which "focuses on the distribution of pharmaceuticals and related services to physician[s'] offices, and services for biotech and specialty pharmaceutical manufacturers"—is a subsidiary of ABC, a pharmaceutical wholesaler and service provider (27). IPN and ION are subsidiaries

or divisions of ABSG and "comprise physician services networks in various medical specialties" (27).

In April 2010, Relators filed the TAC. Like the Second Amended Complaint, the TAC names six defendants: Amgen, U.S. Oncology and the four ABC Defendants. However, unlike the prior pleadings, each of which alleged only four federal causes of action, the TAC contains 26 causes of action: four claims under the FCA and claims alleging violations of 21 state laws analogous to the FCA and the District of Columbia False Claims Act (collectively, the "State-law Claims"). With the filing of the TAC, Relator now brings this action not only on behalf of the United States, but also on behalf of 21 states and the District of Columbia (collectively, the "States").

Sometime prior to December 20, 2012, Amgen, the United States, the States and the relators in ten other *qui tam* actions filed against Amgen reached a settlement of the claims regarding Amgen's marketing and promotion of certain drugs. Relators decided not to join in that settlement. However, Relators did file an "Agreed Motion to Dismiss Relators' State Law Claims against Amgen with Prejudice," in which Relators, with the States' consent, sought to voluntarily dismiss with prejudice the State-law Claims against Amgen pursuant to Fed. R. Civ. P. 41(a)(2). That motion was granted in an order dated January 16, 2013.

In a "Notice of Declination in Part" dated and filed on December 19, 2012, the United States declined to intervene in this action except to the extent of filing a

motion to dismiss with prejudice the claims brought on its behalf against Amgen. In February 2013, the United States filed that motion, which raised four grounds: (1) that Relators failed to plead the FCA and analogous state-law claims with particularity, as required by Federal Rule of Civil Procedure 9(b); (2) that the "public disclosure bar" set forth in 31 U.S.C. §§ 3730(e)(4) barred this action; (3) that the first-to-file rule set forth in 31 U.S.C. §§ 3730(b)(5) required that this action be dismissed without prejudice; and (4) that 31 U.S.C. § 3730(c)(2)(A) permits the Government to dismiss a *qui tam* action as a matter of prosecutorial discretion. In a memorandum and order dated September 30, 2013, the Court granted the motion to dismiss on the fourth ground, but did not address the first three arguments. *See United States ex rel. Piacentile v. Amgen Inc.*, No. 04-CV-3983 (SJ)(RML), 2013 WL 5460640 (E.D.N.Y. Sept. 30, 2013).

In light of this memorandum and order, the Clerk of Court entered a "judgment" dated November 1, 2013, which "adjudged that the government's motion to dismiss is granted; and that the Relators' motion to amend the Third Amended Complaint is denied as futile." After Relators appealed, the Second Circuit issued a mandate dated March 11, 2014, which remanded the case and directing the Court to "clarify whether it intended to grant judgment on the entire case … or only on the claims against Amgen." The mandate expressly authorized the Court, "upon consultation with the parties, to revoke its judgment … and enter a new judgment." The Second Circuit noted that if the Court entered a new

judgment which adjudicated only a part of the action, it "should specify in the judgment whether the partial judgment should be deemed final, as authorized by Rule 54(b)." The mandate also provided that any party to the appeal could restore jurisdiction to the Circuit Court by simply sending a letter to the Clerk of the Court of Appeals within 30 days after this Court's decision.

In letters filed with this Court within 15 days of the Second Circuit's mandate, both the United States and Relators recommended that the Court clarify that the judgment applied only to the claims against Amgen and opined that it might be appropriate to enter a final partial judgment against Amgen, permitting relators to take an immediate appeal of the order dismissing Amgen. However, the Government noted that if the claims against the remaining defendants were resolved, "there would be no need for certification pursuant to Rule 54(b) and no question of whether judicial economy was served by such certification." Letter to Hon. Sterling Johnson, Jr., from Deborah B. Zwany, dated Mar. 24, 2014, p. 3.

At a status conference on March 28, 2014, U.S. Oncology requested permission to move to dismiss the claims against them. Relators stated that they wished to voluntarily dismiss the claims against the ABC Defendants. Accordingly, the Court set a briefing schedule for the motion to dismiss and

directed Relators to file a stipulation of discontinuance with respect to the ABC Defendants.[2]

Relators filed a stipulation dismissing all claims against the ABC Defendants on April 11, 2014. On that same day, the States filed a Notice of Declination to Intervene, declining to intervene with respect to Relators' State-law Claims against U.S. Oncology. Accordingly, Relators are the only plaintiffs in this action and U.S. Oncology is the only remaining defendant.

The TAC's Allegations Regarding U.S. Oncology

Most of the allegations in the TAC relate to Amgen and its illegal or unlawful practices. However, because U.S. Oncology is the movant herein, this summary of the allegations of the TAC focuses primarily on the allegations relating to U.S. Oncology.

The TAC describes U.S. Oncology as operating in two distinct capacities. First, in paragraph 7, the TAC describes the defendant as a "physician's network," whose "network physicians" have received "illegal remuneration and kickbacks" from Amgen and have "prescribed large volumes of Amgen drugs to Medicaid and

[2] Although the Court's actions implied that the judgment dated November 1, 2013, did not pertain to the entire case, the Court did not formally vacate the judgment at that time. In the interests of clarifying the record, the Court will enter an order vacating that judgment. Since Relators have stipulated to the entry of an order dismissing their claims against Amgen and have waived their right to appeal the Court's September 30, 2013, decision or the November 1, 2013, judgment (Dkt. No. 161), the Court perceives no need to enter a partial judgment or to consider the question of whether to direct entry of a final partial judgment at this time. *See* Fed. R. Civ. P. 54(b).

Medicare patients and beneficiaries of other government healthcare programs in violation of federal and state laws." According to paragraph 7, U.S. Oncology "conducts all billing for its network physicians," and has "submitted claims to Medicaid, Medicare and other government healthcare programs" in this capacity.

Second, in paragraph 26, the TAC implies that U.S. Oncology is itself a healthcare provider, noting that Defendant "has cancer treatment centers in 39 states." The paragraph further alleges, on information and belief, that "U.S. Oncology bills Medicare and Medicaid for Amgen pharmaceuticals at a rate of more than $60 million a year." This implies that U.S. Oncology does not merely bill for network physicians, but files claims on its own behalf.

On or about February 28, 2002, U.S. Oncology "entered into a multi-year agreement" with Amgen (133). Although the TAC alleges that this agreement pertained to Aranesp, Neulasta and Neupogen and was "worth approximately $250 million per year" (133), the exact terms of the contract are not alleged. Rather, the TAC alleges—based on Piacentile's conversations with parties to the negotiations—that U.S. Oncology demanded "unlawful financial incentives that included Amgen paying grants, giving drug discounts and rebates, and sponsoring physician speakers, advisory boards and conferences, all to U.S. Oncology or for the benefit of its physician members" (135). In addition, U.S. Oncology "made clear that ... Amgen would have to provide incentives that exceeded those provided by U.S. Oncology's then-current supplier of competing drugs" (136).

Although the TAC states that "Amgen agreed to provide these incentives" (137), the TAC is vague with respect to what "incentives" were provided. The TAC expressly alleges that Amgen paid "kickbacks to U.S. Oncology and its network physicians" (90), and that these kickbacks included "cash payments, so-called research grants, free services, free equipment and other inducements" (88). The TAC also implies that Amgen's agreement with U.S. Oncology provided for "illegal remuneration" (7) and "price discounts" (139), and expressly alleges that the discounts, rebates and other financial incentives obtained from Amgen go "to U.S. Oncology or for the benefit of its physician members" (135).

The TAC also expressly alleges that an Amgen sales representative admitted to Piacentile that Amgen paid U.S. Oncology's pharmacy director, William Faines, $5,000 to talk to doctors about the effectiveness of Amgen drugs (97). In the preceding paragraph, the TAC alleges that Amgen routinely paid "honoraria" and "speaking fees" to physicians and nurses with authority to recommend pharmaceutical purchases, and that the "fees were usually given as a reward to physicians who prescribed a satisfactory quota of Amgen drugs" (96). However, the TAC does not allege that Faines had the authority to purchase drugs on behalf of U.S. Oncology and alleges that Amgen—through a contractor, Health Dimensions—sometimes paid "influential individuals within the medical community, many of who[m] sit on formulary committees or are clinical pharmacists," to lecture other providers on prescribing Amgen drugs (118).

Accordingly, the TAC does not make it clear whether the $5,000 paid to Faines was a reward for purchasing drugs or a fee for lecturing other doctors on behalf of Amgen.

In addition, the TAC alleges that U.S. Oncology received excessive "data fees" from Amgen that were not set forth in the agreement. Specifically, the TAC alleges that "[f]or the years 2000 to 2002, U.S. Oncology collected data fees from 3 percent to as much as 6 percent of the total volume of drugs purchased by U.S. Oncology on behalf of its network physicians, although the actual cost of collecting data is only approximately one half of one percent of the purchase price" (145). According to the TAC, the "purported 'data fees'"—which a former Amgen sales executive characterized as "bogus"—amounted to over $5 million during an unspecified one-year period (146), but "were not set in advance by contract and were not disclosed to the government" (147). The TAC also alleges that "U.S. Oncology has knowingly refused to disclose to the government the rebates and data fees it receives from manufacturers" (154).

The Federal Causes of Action

None of the four federal causes of action specifically mention U.S. Oncology or point to specific facts making out an FCA violation. Rather, all four causes of action consist of two paragraphs: one stating that "Relators repeat and incorporate by reference the allegations contained" in all preceding paragraphs and another alleging that, "[a]s more particularly set forth in the foregoing paragraphs,

by virtue of the acts alleged herein the defendants" have violated a specific provision of the FCA.

The second paragraph does little more than track the language of the subsection of the FCA which was allegedly violated. The first cause of action alleges that "defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A)" (159). The second cause of action charges that "defendants have knowingly made, used, or caused to be made or used false records or statement—*i.e.*, the false certifications and representations made or caused to be made by defendants—material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B)" (161). The third cause of action alleges that "defendants knowingly made, used, or caused to be made or used false records or false statements—*i.e.*, the false certifications made or caused to be made by defendants—material to an obligation to pay or transmit money or property to the Government or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the United States," in violation of 31 U.S.C. § 3729(a)(1)(G) (163). The fourth cause of action charges that "defendants conspired to get false or fraudulent claims paid by the United States and performed one or more acts to effect payment of false or fraudulent claims by the United States" (165).

These causes of action do not identify specific false claims or false certifications, and the paragraphs preceding the causes of action do little to elucidate Relators' theory. For example, paragraph 5 alleges that "Amgen has caused or induced physicians … to file false, and/or fraudulent, certifications regarding compliance with the Anti-Kickback Statute and the Medical Rebate Statute. Two paragraphs later, the TAC alleges that it was U.S. Oncology who filed the claims on behalf of its network physicians and that the claims themselves "were fraudulent because they sought reimbursement for Amgen drugs at rates significantly above the levels the network physicians would receive had they disclosed the kickbacks and price discounts they received from Amgen to the federal and state governments." In paragraph 9, the TAC reverts to the false certification theory, but without specifying who filed the certifications. Paragraph 9 alleges that unspecified "defendants falsely certified … that they claims they submitted or caused to be submitted were made in compliance with federal law, including the prohibitions against kickbacks and illegal remuneration to physicians."

The TAC does not provide the dates—or even a range of dates—on which U.S. Oncology filed the allegedly false claims at issue in this case. At most, the pleading implies that the claims were filed sometime after February 28, 2002—the date on which Amgen and U.S. Oncology inked their "multi-year agreement" (133). In addition, the TAC does not identify the federal healthcare programs to

which these claims for reimbursement were filed. At most, the pleading alleges five federal healthcare programs which might theoretically have received those claims: Medicare, Medicaid, Tricare (formerly known as the Civilian Health and Medical Program of the Uniformed Services), the Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") and the Federal Employees Health Benefits Program ("FEHB") (28-36).

The State-Law Claims

Each of the 22 State-law Claims alleges a violation of a different state law analogous to the FCA or, in the case of the twenty-sixth cause of action, a violation of the District of Columbia False Claims Act. Nonetheless, all 22 causes of action consist of six nearly identical paragraphs. The first paragraph states that "Relators repeat and incorporate by reference the allegations contained" in all preceding paragraphs. The second paragraph alleges that "[b]y virtue of the acts described" in the preceding paragraphs, unspecified "Defendants knowingly presented or caused to be presented, false or fraudulent claims … for payment or approval" to a particular state government. The third paragraph charges that "[b]y virtue of the acts described" in the preceding paragraphs, "Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce" the particular state government "to approve and pay such false and fraudulent claims."

The fourth paragraph alleges that the particular state government, being "unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants" as alleged in the TAC. The fifth paragraph alleges that, "[b]y reason of the Defendants' acts," the particular state "has been damaged, and continues to be damaged, in a substantial amount to be determined at trial." The sixth and final paragraph alleges that pursuant to the particular state law allegedly violated by Defendants, the state "is entitled to three times the amount of actual damages plus the maximum penalty" allowed by the statute "for each and every false or fraudulent claim, record or statement made, used, presented or cause to be made, used or presented by Defendants." However, none of these causes of action identify any false claims filed by U.S. Oncology with the particular state, or in violation of the state law, identified in the cause of action.

U.S. Oncology's Motion to Dismiss

U.S. Oncology now moves to dismiss the TAC. In its Memorandum of Law in Support of U.S. Oncology's Motion to Dismiss ("Defendant's Memo"), Defendant principally argues that the TAC fails to meet the pleading standards of Fed. R. Civ. P. 8(a) and 9(b) in several respects. First, U.S. Oncology argues that the TAC does not allege particularized facts plausibly suggesting that the discounts, kickbacks and "data fees" provided by Amgen violated the AKS or that U.S.

Oncology knew that they did not fit within a statutory or regulatory "safe harbor." Second, Defendant argues that even if the TAC adequately alleged a violation of the AKS, it did not adequately allege a "false certification of compliance." Third, U.S. Oncology notes that the TAC does not allege a single "false claim" for payment, much less with the specificity required by Rule 9(b). Fourth, U.S. Oncology argues that the TAC does not allege that the "data fees" paid by Amgen were to induce U.S. Oncology to generate purchases of Amgen drugs.

Defendant urges the Court to dismiss the case with prejudice at this juncture, arguing that Relators cannot make out an FCA claim for two reasons. First, Defendant argues that "Relators *cannot* allege an AKS violation" because there is "insurmountable evidence" that the discounts and rebates fell within an exception to the AKS. Defendant's Memo, p. 9 (emphasis in original). Second, Defendant argues that "Relators could never allege" that U.S. Oncology falsely certified compliance with the AKS because U.S. Oncology is only a Group Purchasing Organization, or "GPO," and "does not submit claims for reimbursement to the Government in connection with the GPO services that it provides to its members [or] … make any kind of certification of compliance with the AKS." *Id.*, p. 13.

In support of these arguments, Defendant has submitted an agreement between Amgen and U.S. Oncology entitled "Amendment #2 to Agreement No. 19990127," which is attached as Exhibit 1 to the Declaration of Ryan G.

Hassanein, one of Defendant's attorneys (the "Hassanein Declaration"). Although this document is dated February 27, 2002, Defendant argues that this is the "multi-year agreement," signed "[i]n or about February 28, 2002," which is incorporated by reference in paragraph 133 of the TAC. This agreement states that U.S. Oncology is a GPO, and will be compensated through an "administrative fee." Hassanein Declaration, Ex. 1, pp. 1-2. It further provides that U.S. Oncology's members will receive an upfront discount, plus volume-based rebates, when they purchase Amgen products through "authorized wholesalers," and "must account for any discount or rebate earned" and "accurately report the value of such discount in any charges or cost reports filed." *Id.*

In a two-page section at the end of Defendant's Memo, U.S. Oncology advances four arguments for dismissing some of Defendant's State-law claims. First, U.S. Oncology argues that the Rule 8(a) and 9(b) pleading requirements also apply to claims pursuant to state false claim statutes. Second, assuming that all of Relators' claims pre-date the filing of the original complaint, U.S. Oncology argues that Relator cannot raise claims pursuant to the Georgia, Indiana, New Jersey, New Mexico, New York, Oklahoma, Rhode Island and Wisconsin false claims statutes because those laws were not enacted until after September 2004. Third, U.S. Oncology argues that the twelfth cause of action, which raises claims under the Louisiana Medical Assistance Programs Integrity Law, should be dismissed because Relators have not complied with the law's requirement that they disclose

to Louisiana "all material evidence and information ... within one year of the date [they] knew or should have known of the information forming the basis of the complaint." Defendant's Memo, p. 18 (quoting La. Rev. Stat. Ann. §§ 46:439.1(C) & 46:439.2(A)(2)(b) (1997)). Fourth, U.S. Oncology argues that the twenty-third cause of action, which raises claims under the Texas Medicaid Fraud Prevention Act, should be dismissed "because the *qui tam* provisions in effect during the relevant period do not allow *qui tam* suits to proceed without intervention by the State." *Id.*, pp. 18-19.

Relators' Memorandum of Law in Opposition to Defendant's Motion to Dismiss ("Relators Opposition") addresses most of the arguments raised in Defendant's Memo. Relators' arguments are discussed, as necessary, in the Discussion below.

DISCUSSION

I. Rules 8(a) and 9(b)

Generally, a pleading need only contain "(1) a short and plain statement of the grounds for the court's jurisdiction ... ; (2) a short and plain statement of the claim showing that the pleader is entitled to relief; and (3) a demand for the relief sought ...." Fed. R. Civ. P. 8(a). However, when "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Even when Rule 9(b) applies, "knowledge ... and other conditions of a person's mind may be alleged generally." *Id.*

Since it is "self-evident that the FCA is an anti-fraud statute[,] … courts routinely require FCA claims to comply with Rule 9(b)." *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995). Ordinarily, Rule 9(b) "requires a complaint alleging fraud to (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) (quoting *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016)). "The purpose of Rule 9(b) is threefold—it is designed to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *United States ex rel. Ladas*, 824 F.3d at 25 (quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991). The Second Circuit recognizes and rigorously enforces "these salutary purposes of Rule 9(b)." *Id.* (quoting *Ross v. Bolton*, 904 F.2d 819, 823 (2d Cir. 1990)).

"Despite the generally rigid requirement [of Rule 9(b)], allegations may be based on information and belief when facts are peculiarly within the opposing party's knowledge." *United States ex rel. Chorches*, 865 F.3d at 81-82 (quoting *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990)). Still, a plaintiff alleging fraud on information and belief must have "sufficient data to justify

interposing an allegation on the subject" and the complaint must "adduce specific facts supporting a strong inference of fraud." *Id.* at 82 (internal quotations and citations omitted). *Wexner*, 902 F.2d at 172. Similarly, "while Rule 9(b) permits scienter to be demonstrated by inference, this 'must not be mistaken for license to base claims of fraud on speculation and conclusory allegations.'" *O'Brien*, 936 F.2d at 676 (quoting *Wexner*, 902 F.2d at 172).

Analysis of Defendant's Rule 9(b) arguments is complicated by three factors. First, Relators' causes of action contain no factual allegations whatsoever, leaving it to the reader to scour more than 150 paragraphs of factual allegations and to guess which allegations apply to each of the 26 causes of action. Second, the four federal causes of action cite to sections of 31 U.S.C. § 3729 which were amended in 2009 and may not be applicable to conduct preceding the May 20, 2009—the date on which the amendments were enacted. Third, in arguing that the TAC fails to satisfy the requirements of Rules 8(a) and 9(b), Defendant does not distinguish between the various causes of action. As discussed below, the TAC contains many allegations in support of some causes of action, and virtually no allegations concerning others.

A. The TAC's First Cause of Action

The first cause of action alleges a violation of 31 U.S.C. § 3729(a)(1)(A) (2009). That subsection was added by the Fraud Enforcement and Recovery Act ("FERA"), Pub. L. No. 111–21, 123 Stat. 1617, 1621 (2009), and is applicable only

to conduct which occurred on or after May 20, 2009, the date on which FERA was enacted. *See* FERA § 4(f), 123 Stat. at 1625. Since the TAC does not allege when U.S. Oncology filed the allegedly false claims, it is unclear whether 31 U.S.C. § 3729(a)(1)(A) or its predecessor, 31 U.S.C. § 3729(a)(1) (1994), or both, apply to this case.

This ambiguity does not impede the Court's analysis of this cause of action because the language of § 3729(a)(1)(A) is almost identical to that of the former § 3729(a)(1). Both versions impose liability on "any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the federal Government. To state a claim under either version, a relator must prove that the defendant "(1) made a claim, (2) to the United States Government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001), *abrogated on other grounds by Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. —, 136 S. Ct. 1989 (2016); *Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 43 & n.1 (2d Cir. 2016) (using the pre-amendment elements while stating, in a footnote, that the amendments "do not materially alter" the analysis), *cert. granted, judgment vacated on other grounds*, 137 S. Ct. 1067 (2017).

Three of Defendant's Rule 9(b) arguments are applicable to this cause of action. First, U.S. Oncology argues that this cause of action does not allege a

single "false claim," much less with the specificity required by Rule 9(b). Second, the Defendant argues that Relators do not adequately allege a "false certification" theory. Third, U.S. Oncology argues that the TAC does not allege that it knew that the claim was false.

The Court agrees with Defendant that the allegations lack the particularity required by Rule 9(b). First, the TAC does not adequately identify the false claims for which Relators seek to recover. The Court is not troubled by Relators' inability to list specific claims. The Court is troubled, however, by the TAC's failure to specify even a range of dates during which the claims were made. Although Relators Opposition alleges that the TAC "provides many details regarding the exact timeframe within which false claims were submitted," Relators Opposition's own allegations belie this claim. Relators cites to five paragraphs in the TAC that allegedly support this claim, but only three actually mention any dates: paragraph 133, which alleges that U.S. Oncology and Amgen entered into a "multi-year" agreement "[i]n or about February 28, 2002;" paragraph 145, which alleges that U.S. Oncology collected data fees from 2000 to 2002, and paragraph 148, which alleges that Amgen "will likely pay a rebate of more than $500,000 for 2003 purchases" to "a clinic U.S. Oncology advises in Morristown, N.J."[3] None of these

[3] The other two paragraphs are 142 (alleging that an unnamed network physician was "typically able to glean $300,000 per quarter from Amgen discounts and incentives by paying a $44,000 monthly fee to U.S. Oncology") and 146 (alleging that, during some unspecified year, Amgen paid U.S. Oncology $5 million in data fees).

paragraphs mention false claims, much less allege dates, or even an approximate range of dates, on which U.S. Oncology filed false claims.

Even if they did, these factual allegations might support, at most, allegations that U.S. Oncology filed false claims in the early part of the last decade. They would not support Relators allegation "that the violations in the TAC continued beyond 2003." Relators Opposition, p. 18, n. 6. To the extent that the TAC is alleging that U.S. Oncology continues to file fraudulent claims, that allegation appears to rest solely on "speculation and conclusory allegations." *See O'Brien*, 936 F.2d at 676; *Wexner*, 902 F.2d at 172.

Second, the TAC does not adequately explain the theory of liability that Relators intend to pursue. The TAC clearly alleges that U.S. Oncology negotiated a contract with Amgen that enabled network physicians to receive discounts, rebates and other financial incentives for prescribing Amgen drugs. In addition, by repeatedly characterizing these incentives as "kickbacks," the TAC at least implies that they violated the AKS. The TAC then alleges that U.S. Oncology "conducts all billing for its network physicians" (7), implying that U.S. Oncology filed claims on behalf of its customers. These allegations, read together, suggest an express or implied false certification theory: that Defendant filed, or caused to be filed, claims for Government reimbursement that, either expressly or implicitly, falsely certified compliance with the AKS.

Some allegations in the TAC suggest that Relators are relying on an express false certification theory, but offer conflicting accounts of who made the false certifications. In paragraph 5, the TAC alleges that "Amgen has caused and/or induced physicians who sought reimbursement for Amgen drugs from federal government-funded health insurance programs to file false, and/or fraudulent, certifications regarding compliance" with the AKS and MRS. This suggests that the network physicians expressly certified compliance with the AKS and MRS, and that U.S. Oncology caused the certificates to be filed. In contrast, paragraph 9 states that "defendants falsely certified … that the claims they submitted or caused or be submitted were made in compliance with federal law, including the prohibitions against kickbacks and illegal remuneration to physicians." Although the paragraph does not identify the "defendants," it clearly alleges that these defendants, not the network physicians, made the false certifications.

Other sections of the TAC suggest entirely different theories of liability. Paragraph 7 explains that the claims filed by U.S. Oncology "were fraudulent because they sought reimbursement for Amgen drugs at rates significantly above the levels the network physicians would receive had they disclosed the kickbacks and price discounts they received from Amgen to the federal and state governments." This suggests that the physicians had an affirmative duty to disclose the kickbacks and discounts to the government. Paragraph 140, however, alleges that U.S. Oncology "routinely escalates the reimbursement rate for the drugs it

purchases from Amgen," suggesting that U.S. Oncology itself is engaging in misreporting.

As if these contradictory allegations were not confusing enough, Relators Opposition subtly revises other allegations of the TAC. For example, paragraph 11 alleges that "[b]y intentionally concealing both the payment of kickbacks and price discounts to U.S. Oncology, … Amgen failed to accurately report the "best price" of Medicaid covered drugs as required by the [MRS]." Relators Opposition, however, claims that this paragraph alleges that U.S. Oncology's "intentional concealment of the receipt of kickbacks and price discounts resulted in Amgen's failure to accurately report the 'best price' of covered drugs to the Government." Relators Opposition, p. 6. It does not.

Similarly, paragraphs 145 and 147 allege that from 2000 to 2002, U.S. Oncology collected "data fees" from Amgen that were "grossly inflated," "tied to the market share of the drug that is purchased," and "not reported to the government." Relators Opposition states that it "plausibly follows" from these allegations that the data fees "were used to induce increased prescriptions of Amgen's oncology drugs that are indisputably used on patients covered by government funded health care programs." Relators Opposition, p. 11. This theory—presumably, that the "data fees" induced U.S. Oncology to over-prescribe Amgen drugs at the 39 cancer treatment centers which it operates—is not at all apparent from the allegations of the paragraphs 145 and 147.

The Court does not mean to imply that Relators are not permitted to assert alternative or inconsistent theories of liability. "[L]itigants have substantial leeway … to plead alternative, and even inconsistent, claims," provided that those theories are supported by factual allegations sufficient to "raise a right to relief above the speculative level." *Kwan v. Schlein*, 246 F.R.D. 447, 451 (S.D.N.Y. 2007). However, defendants are entitled to "fair notice of a plaintiff's claim." *United States ex rel. Ladas*, 824 F.3d at 25; *O'Brien*, 936 F.2d at 676. The TAC leaves the reader guessing as to Relators' theories of liability.

Third, the TAC does not specifically allege that U.S. Oncology knew that the claims it filed on behalf of its customers were false. To the extent that the first cause of action relies on an implied false certification theory, U.S. Oncology would have to know that by filing a Medicaid and Medicare claim it was implicitly certifying compliance with the AKS. Although Relators assert that it is "beyond cavil that claims submitted in violation of the Anti-Kickback Statute 'qualify as False Claims under the FCA,'" Relators' Opposition, p. 7, the Court notes that Relators cite to three out-of-Circuit, district court opinions in support of that proposition.

Prior to 2011, when the AKS was amended to expressly state that "a claim that includes items or services resulting from a violation of [the AKS] … constitutes a false or fraudulent claim for purposes of [the FCA]," 42 U.S.C. §

1320a-7b(g), that proposition was far from clear in this Circuit.[4] In *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), *abrogated by Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989 (2016), the Second Circuit held that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." *Id.* at 700. In 2002, a district court observed that the issue of whether a *qui tam* relator could "use the FCA as a vehicle for pursuing a violation of the anti-kickback statute in this Circuit" was "hotly disputed and controversial." *United States ex rel. Barmak v. Sutter Corp.*, No. 95 Civ. 7637 (KTD)(RLE), 2002 WL 987109, at *5 (S.D.N.Y. May 14, 2002). As of 2014, the Second Circuit had not "decided whether compliance with the AKS is a precondition to the payment of claims submitted to Medicare or Medicaid." *United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 263 (S.D.N.Y. 2014). Accordingly, even assuming that U.S. Oncology knew that the discounts, rebates and other incentives its network physicians obtained from Amgen were illegal remuneration, U.S. Oncology might not have known that claims for Government reimbursement

[4] That amendment, which became effective on January 1, 2011, does not provide for retroactive application. *United States v. New York Soc. for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 Civ. 292 (PKC), 2014 WL 3905742, at *19 (S.D.N.Y. Aug. 7, 2014).

which it filed on behalf of those physicians implicitly certified the physicians' compliance with the AKS and were, therefore, false.

B. The TAC's Second Cause of Action

The second cause of action alleges a violation of 31 U.S.C. § 3729(a)(1)(B) (2009). Although the TAC does not allege when U.S. Oncology filed the allegedly false claims, § 3729(a)(1)(B)—and not its predecessor, 31 U.S.C. § 3729(a)(2) (1994)—is applicable to claims that were pending on or after June 7, 2008. *See* FERA § 4(f), 123 Stat. at 1625. Because Relators' second cause of action has been pending since 2004, § 3729(a)(1)(B) applies.

"[T]o establish a cause of action under § 3729(a)(1)(B), the … relator must show that defendants knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim." *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 335 (9th Cir. 2017) (citing *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1048 (9th Cir. 2012)). Relators' second cause of action has the same defects as the first. First, although it refers to "false certifications and representations made or caused to be made by defendants" (161), it does not adequately identify who made the false certifications or representations, when they were made, or to which government healthcare program they were made. Second, the second cause of action does not provide adequate notice of the theory of liability Relators intend to pursue. Third, the TAC does not specifically allege that U.S. Oncology knew that the certifications or representations were false.

C. The TAC's Third Cause of Action

The third cause of action alleges a violation of 31 U.S.C. § 3729(a)(1)(G).[5] This subsection is sometimes "referred to as the 'reverse false claims' provision because 'it covers claims of money *owed* to the government, rather than payments *made* by the government.'" *United States ex rel. Kester v. Novartis Pharm. Corp.*, 43 F. Supp. 3d 332, 368 (S.D.N.Y. 2014)(quoting *United States ex rel. Capella v. Norden Sys., Inc.*, No. 94 Civ. 2063, 2000 WL 1336487, at *10 (D.Conn. Aug. 24, 2000) (emphasis added in *United States ex rel. Kester*). "To prove a claim under subsection (a)(1)(G), a plaintiff must show: (1) 'proof that the defendant made a false record or statement' (2) at a time that the defendant had a presently-existing 'obligation' to the government—'a duty to pay money or property.'" *Id.* (quoting

[5] Like subsection (a)(1)(A), this subsection was added by FERA in 2009, took effect on May 20, 2009, and applies only to conduct occurring on or after that date. *See* FERA § 4(f), 123 Stat. at 1625. Since the TAC does not allege when U.S. Oncology filed the allegedly false claims, it is unclear whether 31 U.S.C. § 3729(a)(1)(G) or its predecessor, 31 U.S.C. § 3729(a)(7) (1994), or both, apply to this case.

In some instances, the determination of what version of § 3729 applies could prove significant because §3729(a)(1)(G) differs from its predecessor. Subsection 3729(a)(7) provided that any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government" would be liable under the FCA. Subsection (a)(1)(G) provides that any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government" is liable. However, the determination of what version applies is not crucial to the Court's Rule 9(b) analysis.

Chesbrough v. VPA, P.C., 655 F.3d 461, 473 (6th Cir. 2011)). "Where a complaint 'makes no mention of any financial obligation that the [defendants] owed to the government,' and 'does not specifically reference any false records or statements used to decrease such an obligation,' the court should dismiss the subsection (a)(1)(G) claim." *Id.* (quoting *Wood ex rel. United States v. Applied Research Assocs., Inc.*, 328 Fed. App'x 744, 748 (2d Cir. 2009) (amended summary order)).

The Court assumes that the third cause of action relates to the MRS—the only provision mentioned in the TAC which obligates any of the defendants to pay money to the Government. However, according to the TAC, the MRS obligates drug manufacturers to report "best price" information to the CMS and to pay rebates calculated from this information. TAC, ¶ 55. The TAC does not alleges that this statute imposed any financial obligation on U.S. Oncology, much less explain how false records or statements filed by U.S. Oncology decreased such an obligation. Accordingly, even assuming that Relators are attempting to state a § 3729(a)(1)(G) cause of action against U.S. Oncology, the third cause of action must be dismissed pursuant to Rule 9(b). *See Wood ex rel. United States*, 328 Fed. App'x at 748.

D. The TAC's Fourth Cause of Action

The fourth cause of action alleges a violation of 31 U.S.C. § 3729(a)(1)(C). Like subsections (a)(1)(A) and (a)(1)(G), this subsection was added by FERA in 2009, took effect on May 20, 2009, and applies only to conduct occurring on or

after that date. *See* FERA § 4(f), 123 Stat. at 1625. Since the TAC does not allege when U.S. Oncology filed the allegedly false claims, it is unclear whether 31 U.S.C. § 3729(a)(1)(C) or its predecessor, 31 U.S.C. § 3729(a)(3) (1994), or both, apply to this case. However, the language of the former § 3729(a)(3) is nearly identical to that of current § 3729(a)(1)(C). Subsection (a)(3) imposed liability on "any person who … conspires to commit a violation" of any of the other subsections of § 3729(a). Similarly, subsection (a)(1)(C) imposes liability on any person who conspires to commit a violation of the other subsections of § 3729(a)(1).

Preliminarily, the Court notes that there is some dispute as to whether Rule 9(b) applies to these sorts of conspiracy claims. The First, Sixth, Eighth and Eleventh Circuits have held that it does. *See United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009); *United States ex rel. Marlar v. BWXT Y–12, L.L.C.*, 525 F.3d 439, 445 (6th Cir. 2008); *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006); *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005) (per curiam). However, the "Second Circuit has not decided whether (and, if so, how) Rule 9(b) applies to subsection (a)(1)(C), and district courts in this Circuit seem to have diverged on the question." *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 825 (S.D.N.Y. 2017) (citing district court cases), *rev'd on other grounds*, 899 F.3d 163 (2018).

Neither party addresses this issue in their motion papers. Although Relators Opposition tacitly concedes that Rule 9(b) applies by arguing that the TAC "alleges a conspiracy … with the particularity required by R. 9(b)," Relators Opposition, p. 17, the Court need not decide this question. The allegations of conspiracy in the TAC do not even satisfy the Rule 8 standard.

"To state a claim under this subsection, a relator must show that: '(1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States' and '(2) one or more conspirators performed any act to effect the object of the conspiracy.'" *United States ex rel. Wood*, 246 F. Supp. 3d at 825 (quoting *United States ex rel. Taylor v. Gabelli*, 345 F.Supp.2d 313, 331 (S.D.N.Y. 2004)). Here, the TAC does not use the word "conspiracy" except in the fourth cause of action. Even there, the TAC does not specify "the defendants" who allegedly participated in the alleged conspiracy.

Moreover, while Relators Opposition asserts that the TAC "provides significant evidence of a conspiracy between Amgen and [U.S. Oncology]," Relators Opposition, p. 21, even that submission does not allege a conspiracy to violate the FCA. Rather, Relators Opposition asserts that Amgen and U.S. Oncology conspired to "funnel" or "pass" kickbacks to U.S. Oncology's member physicians in order "to cause them to prescribe Amgen's drugs." *Id.*, pp. 17, 21. Relators do not allege that Amgen knew, or cared, who would pay the cost of the

drugs, or that the parties shared the objective of getting claims paid by the Government.

E. Leave to Amend

Relators specifically request leave to amend their pleading if the Court perceives deficiencies in the TAC. Relators Opposition, p. 23. "Complaints dismissed under Rule 9(b) are 'almost always' dismissed with leave to amend," *Pasternack v. Shrader*, 863 F.3d 162, 175 (2d Cir. 2017), unless "plaintiffs have ... already had one opportunity to plead fraud with greater specificity or the defective allegations were made after full discovery in a related case." *Luce v. Edelstein*, 802 F.2d 49, 56 (2d Cir. 1986) (internal citations omitted). However, "[l]eave to amend may be denied following a Rule 9(b) dismissal if an amendment would be futile." *Aetna Cas. & Sur. Co. v. Aniero Concrete Co.*, 404 F.3d 566, 584 (2d Cir. 2005) (citing *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 271 (2d Cir. 1996)).

Defendant argues that it would be futile to permit re-pleading in this case because there is "insurmountable evidence" that the discounts and rebates provided by Amgen fell within an exception to the AKS and because U.S. Oncology, as a GPO, "does not submit claims for reimbursement to the Government in connection with the GPO services that it provides to its members [or] ... make any kind of certification of compliance with the AKS." Defendant's Memo, pp. 9, 13. Although this argument relies upon the February 27, 2002, agreement between Amgen and U.S. Oncology, Defendant implicitly urges the Court to engage in Rule

12(b)(6) analysis by noting that "the contract is expressly incorporated by reference in the TAC at Paragraph 133, and is an integral part of the TAC." Defendant's Memo, p. 9 n. 1. Accordingly, before addressing the specifics of Defendant's argument, the Court will briefly review the principles relating to a Rule 12(b)(6) motion.

In considering a motion to dismiss pursuant to Rule 12(b)(6), a court must accept all factual allegations in the complaint as true, and draw all reasonable inferences in the plaintiff's favor. *See Rothstein v. UBS AG*, 708 F.3d 82, 90 (2d Cir. 2013). "Because a Rule 12(b)(6) motion challenges the complaint as presented by the plaintiff, taking no account of its basis in evidence, a court adjudicating such a motion may review only a narrow universe of materials." *Goel v. Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016). Generally, courts "do not look beyond 'facts stated on the face of the complaint, ... documents appended to the complaint or incorporated in the complaint by reference, and ... matters of which judicial notice may be taken.'" *Id.* (quoting *Concord Assocs., L.P. v. Entm't Props. Tr.*, 817 F.3d 46, 51 n. 2 (2d Cir. 2016)). "If, on a motion under Rule 12(b)(6) … , matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d).

In this case, Defendant urges the Court to consider the February 27, 2002, agreement between Amgen and U.S. Oncology, arguing that it is incorporated by

reference. This is unclear, however. The TAC refers to a "multi-year agreement" entered into on or about February 28, 2002, but provides no details regarding the contractual provisions aside from the fact that it pertained to Aranesp, Neupogen and Neulasta and proved to be "worth approximately $250 million per year." TAC, ¶ 133. While it is certainly possible that the February 27, 2002, agreement—despite being entitled, "Amendment #2 to Agreement No. 19990127," *see* Hassanein Declaration, Ex. 1—is the multi-year agreement referenced in the TAC, the Court cannot make this determination based on the sketchy details provided.

Even assuming that the Court could consider the February 27, 2002, agreement, that document would not suffice to establish the truth of the representations contained therein or that U.S. Oncology and its members acted in accordance with that contract. Moreover, many of the contractual representations are expressly contradicted by allegations in the TAC. For example, while the agreement alleges that "U.S. Oncology is an organization that qualifies and acts as a group purchasing organization on behalf of its member[s]," Hassanein Declaration, Ex. 1, p. 1, the agreement does not foreclose the possibility that U.S. Oncology itself also purchases Amgen drugs. The TAC implies that U.S. Oncology not only negotiates on behalf of a "physician's network," but also operates "cancer treatment centers in 39 states," TAC, ¶ 26, and expressly alleges that the discounts, rebates and other financial incentives U.S. Oncology obtained

from Amgen go "to U.S. Oncology *or* for the benefit of its physician members." *Id.*, ¶ 135 (emphasis added).

Indeed, the Court notes that some of the assertions in Defendant's Memo are not substantiated by the agreement, as Defendant claims. For example, Defendant alleges that the discounts and rebates were "fixed" in appendices to the February 27, 2002, agreement and, accordingly, fit within the "safe harbor" or 42 C.F.R. § 1001.952(h)(4). Defendant's Memo, p. 8. This assertion is not substantiated by Exhibit 1 to the Hassanein Declaration, which does not attach any appendices. This assertion is contradicted by the TAC, which expressly alleges that none of the AKS's statutory exceptions and regulatory safe harbors apply. TAC ¶ 40.

Similarly, Defendant's Memo asserts that U.S. Oncology "does not submit claims for reimbursement to the Government in connection with the GPO services that it provides to its members [or] ... make any kind of certification of compliance with the AKS." Defendant's Memo, pp. 9, 13. While the agreement between Amgen and U.S. Oncology represents that U.S. Oncology's members will "account for any discount or rebate earned" and "accurately report the value of such discount in any charges or cost report," Hassanein Declaration, Ex. 1, p. 3, this does not foreclose the possibility that U.S. Oncology could perform these accounting and reporting functions on behalf of their customers. The TAC expressly alleges that U.S. Oncology "conducts all billing for its network physicians," TAC, ¶ 7, and that,

in every claim it filed for government reimbursement, U.S. Oncology falsely certified "compliance with federal law, including the prohibitions against kickbacks and illegal remuneration to physicians." *Id.*, ¶ 9.

In sum, the February 27, 2002, agreement does not establish that Relators will be unable to amend the pleading to state a claim under the FCA. Accordingly, Defendant's motion to dismiss this action without granting Relators permission to replead is denied. This action shall be dismissed without prejudice to amending the pleading within thirty (30) days of the date of this memorandum and order.

II. The State Claims

The remaining 22 causes of action each allege a violation of a different state-law analogue of the FCA. U.S. Oncology argues that the Rule 9(b) pleading requirements also apply to these claims, and that the TAC's state-law claims fail to meet the Rule 9 standard. The Court agrees.

Rule 9(b) "applies to *qui tam* actions under state statutes similar to the FCA." *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-CV-0704 (ERK), 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (citing *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 n. 8 (1st Cir.2007); *Universal Commc'n Sys., Inc. v. Lycos, Inc.*, 478 F.3d 413, 427 (1st Cir. 2007)); and 5A Wright & Miller, *Federal Practice and Procedure*, § 1297 (3d ed. 2004)). The fifth through twenty-sixth causes of action do not come close to satisfying the Rule 9(b) standard. The only allegations of a violation of any state statute are contained in the causes of action

themselves, but none of the state-law causes of action allege any facts. Rather, they contain conclusory allegations that closely track the language of § 3729(a)(1)(A) & (a)(1)(B). Specifically, these causes of action that "Defendants knowingly presented or caused to be presented, false or fraudulent claims" to a state government for "payment or approval," and "knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce" the state government "to approve and pay such false and fraudulent claims." They do not allege which defendants committed these acts or omission; what false claims, records or statement were involved; or when the acts or omissions referenced in these causes of action occurred. Even if the Court could assume that the facts underlying these claims were identical to those underlying the first and second causes of action, these cause of action would fail to meet the Rule 9(b) standard for the same reasons set forth in sections I(A) and (B), *ante*. For the reasons stated in section I(E), *ante*, these 22 causes of action—like the four federal causes of action—are dismissed without prejudice.

Because the State-law Claims do not allege any conduct by U.S. Oncology or the dates on which said conduct occurred, the Court cannot rule on Defendant's claim that the conduct giving rise to eight of Relator's State-law Claims pre-date the enactment of the State statutes alleged to be violated in those claims. Moreover, even if this Court could assume that all of Relator's claims pre-date the filing of the original complaint, U.S. Oncology offers no analysis as to whether any

of the State statutes enacted after 2004 were retroactive. Accordingly, the Court cannot dismiss the eighth, eleventh, seventeenth, eighteenth, nineteenth, twentieth, twenty-first, and twenty-fifth causes of action at this juncture. Nothing herein precludes Defendant from renewing this argument in a motion to dismiss Relators' amended pleading.

For much the same reason, the Court also cannot adjudicate Defendant's motion to dismiss the twenty-third cause of action, which alleges violations of the Texas Medicaid Fraud Prevention Law. This argument relies on the 1997 version of the Texas Human Resource Code § 36.104(b), which required that a court dismiss a *qui tam* action if the State of Texas declined to intervene. Assuming that the conduct giving rise to this cause of action occurred while this version of the law was in effect, Defendant argues that this cause of action must be dismissed because Texas declined to intervene in this action. Defendant's Memo, pp. 18-19.

As Defendant's Memo itself acknowledges, however, § 36.104 was amended in 2007. Defendant's Memo, p. 19. The Civil Remedies and Qui Tam Provisions under the Medicaid Fraud Prevention Act, 2007 Tex. Sess. Law Serv. Ch. 29 (Vernon)—which became effective on May 4, 2007—amended subsection (b) to read: "If the state declines to take over the action, the person bringing the action may proceed without the state's participation." Section 6 of that Act expressly provided:

> This Act applies only to conduct that occurs on or after the effective date of this Act. Conduct that

> occurs before the effective date of this Act is governed by the law in effect at the time the conduct occurred, and that law is continued in effect for that purpose.

Since the twenty-third cause of action does not allege any conduct by U.S. Oncology or the dates on which said conduct occurred, the Court cannot determine whether, and to what extent, the pre-amendment version of Tex. Hum. Res. Code Ann. § 36.104(b) is applicable to this cause of action. Accordingly, the Court cannot dismiss the twenty-third cause of action at this juncture. Nothing herein precludes Defendant from renewing this argument in a motion to dismiss Relators' amended pleading.

In contrast, the Court can adjudicate Defendant's motion to dismiss the TAC's twelfth cause of action, which alleges violations of the Louisiana Medical Assistance Programs Integrity Law. Defendant argues that this cause of action should be dismissed because the TAC does not allege, as required by Louisiana law in effect during the relevant period, that the Relator disclosed to Louisiana "all material evidence and information ... within one year of the date he knew or should have known of the information forming the basis of the complaint." Defendant's Memo, p. 18. However, the statutes cited by U.S. Oncology in support of this argument—La. Rev. Stat. §§ 46:439.1(C) & 46:439.2(A)(2)(b) (1997)—do not require that compliance with those statutes be alleged in the *qui tam* complaint. Section 46:439.1(C) (1997) provided that "[n]o qui tam action shall be instituted later than one year after the date a qui tam complaint is received by the secretary or

the attorney general, whichever occurs first, in accordance with … [section] 46:439.2." Section 46:439.2(A)(2)(b) (1997) stated:

> The qui tam complaint and written disclosure of substantially all material evidence and information shall be filed with the secretary or the attorney general within one year of the date the qui tam plaintiff knew or should have known of the information forming the basis of the complaint. No qui tam action shall be instituted by a qui tam plaintiff if he fails to timely file a complaint with the secretary or the attorney general.

Nothing in La. Rev. Stat. §§ 46:439.1(C) or 46:439.2(A)(2)(b) (1997) expressly requires Relators to *allege* that they disclosed to the State of Louisiana "all material evidence and information … within one year of the date [they] knew or should have known of the information forming the basis of the complaint." Accordingly, Defendant's motion to dismiss the twelfth cause of action is denied. Nothing herein shall be read as precluding Defendant from arguing upon a motion for summary judgment that Relators untimely filed their cause of action pursuant the Louisiana Medical Assistance Programs Integrity Law or failed to timely file the *qui tam* complaint and written disclosure of substantially all material evidence and information with the appropriate state officials.

CONCLUSION

For the reasons stated above, U.S. Oncology's motion to dismiss Relators' Third Amended Complaint pursuant to Rule 9(b) is granted. This action is dismissed without prejudice and with leave to amend within thirty (30) days of the

date of this memorandum and order. If Relators elect to file a Fourth Amended Complaint, U.S. Oncology may move to dismiss that pleading on any of the grounds raised herein, except for the ground that La. Rev. Stat. §§ 46:439.1(C) & 46:439.2(A)(2)(b) (1997) require that Relators' pleading expressly allege that Relators have disclosed to the State of Louisiana "all material evidence and information ... within one year of the date [they] knew or should have known of the information forming the basis of the complaint."

SO ORDERED.

/s/(SJ)

Dated: September 12, 2018
Brooklyn, New York

Sterling Johnson, Jr., U.S.D.J.